K103303

510(k) SUMMARY

DEC 2 3 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. **Submitter's Identification:**

Crosstex International, Inc.
10 Ranick Road
Hauppauge, New York 11788
Tel No.: 631-582-6777
Fax No.: 631-582-1726

Contact Person:

Mr. Gary Steinberg
President
Crosstex International, Inc.
10 Ranick Road
Hauppauge, New York 11788
Tel No.: 631-582-6777
Fax No.: 631-582-1726

Date Summary Prepared: November 4, 2010

2. **Name of Device:**

- Crosstex® Surgical Earloop Mask – White
- Crosstex® Surgical Earloop No Fog Mask – White
- Crosstex® Surgical Earloop No Fog Masks with Splash Visor– White

3. **Predicate Device Information:**

Crosstex Ultra Fluid Resistant No Fog Earloop Face Mask

4. **Device Description:**

The Crosstex Surgical Masks are constructed of a cellulose inner facing, a 100% spunbonded polypropylene white outer facing, a 100% meltblown polypropylene filter media, with white non-latex elastic loops. The nose piece for the Crosstex Surgical Masks is aluminum wire while the no fog strip (if applicable) is made of melt blow polypropylene.

5. **Intended Use:**

The following Crosstex® Surgical Masks are intended for use in infection control practices to minimize contamination caused by inhaled and exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids.

- Crosstex® Surgical Earloop Mask – White
- Crosstex® Surgical Earloop No Fog Mask – White
- Crosstex® Surgical Earloop No Fog Masks with Splash Visor– White

6. **Comparison to Predicate Devices:**

Description	Crosstex Surgical Masks	Predicate Device
Outer Layer	Spunbond Polypropylene	Spunbond Polypropylene
Filter Media	Melt Blown Polypropylene	Melt Blown Polypropylene
Inner Layer	Cellulose	Spunbond Polypropylene
Nose Piece	Aluminum Wire	Aluminum Wire
Attachment	Earloop	Earloop
Anti-Fog (If Applicable)	Melt Blown Polypropylene	Melt Blown Polypropylene
Specifications and Dimensions	Same	7" x 3.5"
Mask Style	Same	Flat Pleated
Sterile	No	No
Single Use	Yes	Yes

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

a. Fluid Resistance: Synthetic Blood Penetration Test
b. Bacterial Filtration Efficiency (BFE) / Differential Pressure ($\triangle$P) Tests
c. Flammability Testing
d. Latex Particle Challenge Test
e. Biocompatibility Testing Per ISO 10993

It was our conclusion that Performance Testing met all relevant requirements of the aforementioned test standards.

8. **Discussion of Clinical Test Performed:**

Not Applicable

9. **Conclusions:**

The Crosstex® Surgical Masks have the same intended use and technological characteristics as the predicate devices. Moreover, bench testing contained in this submission supplied demonstrates that the technological characteristics do not raise any new questions of safety or effectiveness. The Crosstex® Surgical Masks are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Crosstex International, Incorporated
C/O Mr. Richard M. Ormsbee
Minntech Corporation
14605 28th Avenue North
Minneapolis, Minnesota 55447

DEC 23 2010

Re: K103303
Trade/Device Name: Crosstex® Surgical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: December 6, 2010
Received: December 7, 2010

Dear Mr. Ormsbee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

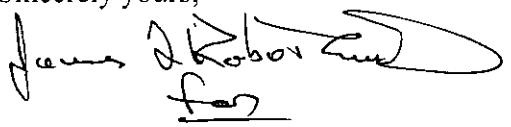
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103303

Indications for Use

510(k) Number (if known): _____

Device Name: Crosstex® Surgical Masks

DEC 2 3 2010

Indications for Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth P. Claverie-Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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